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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	**09/509,482**
Filing Date	**September 15, 2000**
First Named Inventor	**CROFTS, LINDA ANNE**
Group Art Unit	**1646**
Examiner Name	**ULM, JOHN D.**
Attorney Docket Number	**RICE-014**

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Documents
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☒ Petition from Requirement for Restriction pursuant to 37 CFR § 1.144
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):*

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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Signing Attorney/Agent (Reg. No.)	**CAROL L. FRANCIS, 36,513** **BOZICEVIC, FIELD & FRANCIS LLP**
Signature	Carol L. Francis
Date	**June 4, 2003**

#21

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PETITION FROM REQUIREMENT FOR RESTRICTION PURSUANT TO 37 CFR §1.144

Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231

Attorney Docket	RICE-014
First Named Inventor	Linda Anne Crofts et al.
Application Number	09/509,482
Filing Date	September 15, 2000
Group Art Unit	1646
Confirmation Number	9624
Examiner Name	John D. Ulm
Title	"Isoforms of the Human Vitamin D Receptor"

Dear Sir:

Applicants hereby petition the Commissioner to withdraw the Restriction Requirement set out in the above-referenced application in the Office Action dated December 10, 2001 (Paper No. 7), and made final on April 18, 2002 (Paper No. 10), to the extent the Office restricted nucleic acids of a cited sequence identification number (SEQ ID NO) into a Group separate from nucleic acids having a sequence that is a complement of that same SEQ ID NO.

The Restriction Requirement was properly traversed in applicants' response filed on February 11, 2002 (Paper No. 8). Applicants elected to prosecute the subject matter of the claims of Group I with traverse.

As a remedy, applicants request withdrawal of the restriction requirement so that claims drawn to a nucleic acid of a recited sequence and nucleic acid having a complement of that sequence are examined together. Specifically, applicants request that the claims of Groups I and VII be examiner together; that the claims of Groups II and VIII be joined as a single group; and that the claims of Groups III and IX be joined as a single group for future prosecution.

STATEMENT OF THE FACTS

The Office made the following restriction requirement (Office Action dated December 10, 2001):

Group I: Claims 1-4, 9-14 and 21-24, only in so far as they are drawn to an isolated polynucleotide comprising exon 1d (SEQ ID NO:1);

Group II: Claims 5-14 and 21-24, only in so far as they are drawn to an isolated polynucleotide comprising exon 1f (SEQ ID NO:5);

Group III: Claims 5-14 and 21-24, only in so far as they are drawn to an isolated polynucleotide comprising exon 1e (SEQ ID NO:6);

Group IV: Claim 15, drawn to a human protein;

Group V: Claim 16, drawn to an antibody;

Group VI: Claim 17, drawn to a transgenic animal;

Group VII: Claims 19 and 20, only in so far as they are drawn to a polynucleotide which is complementary to a portion of a polynucleotide comprising exon 1d (SEQ ID NO:1);

Group VIII: Claims 19 and 20, only in so far as they are drawn to a polynucleotide which is complementary to a portion of a polynucleotide comprising exon 1f (SEQ ID NO:5);

Group IX: Claims 19 and 20, only in so far as they are drawn to a polynucleotide which is complementary to a portion of a polynucleotide comprising exon 1e (SEQ ID NO:6);

At issue here is whether claims to the polynucleotides of Groups I, II, and III were properly restricted so as to exclude their complements, and probes (claim 19) and antisense polynucleotides (claim 20), which are the subject matter of Groups VII, VIII, and IX, respectively.

In short, applicants' position is that examination of a polynucleotide, its complement, and related polynucleotide probes and antisense molecules, should place no undue burden on the examination process, since a search for art relevant to a given sequence would also identify art relevant to the complement of the sequence. For example, art disclosing a double stranded DNA would necessarily impact the patentability of both strands. Furthermore, art relevant to SEQ ID NO:1, for example, would also be relevant to the patentability of claims directed to probes and antisense molecules.

In addition, there exist numerous instances in which the Office has, in the past, regarded a polynucleotide and its complement as capable of examination within a single application. For example, numerous patents have issued with language that recite a particular polynucleotide "or a complement thereof." See, for example, U.S. Pat. Nos. 6,465,631; 6,465,632; 6,465,717; 6,465,238; and 6,465,232. A search of the USPTO full-text database using the search strategy ACLM/"or complement thereof" and

(ACLM/polynucleotide$ or ACLM/"nucleic acid" or ACLM/DNA) identified over 1,400 issued U.S. patents.

A polynucleotide and its complement are not distinct because they form a complex. That is, the structure of one strand necessarily imposes a certain structure upon the complementary strand. It is well established, for example, that where a recited sequence is 5'-CGAT-3', a complement of that sequence is 5'-ATCG-3', where C pairs with G, and A pairs with T.

In making the Restriction final, the Office took the position that applicants' arguments ignore the breadth of Applicant's probe claims, which only require 10 nucleotides of a polynucleotide of a recited sequence (e.g., SEQ IDNO:1). The Office stated that:

> These different nucleic acids lack a common utility because a nucleic acid encoding a protein can not be employed to detect a corresponding mRNA in a sample and the complement of that nucleic acid can not be employed to produce a protein. Because each is not required for the other, a polynucleotide and its' [sic] complement are distinct chemical compounds.

Office Action mailed April 18, 2002, page 4

To the best of applicants' knowledge, most methods for producing a protein – indeed for even producing the nucleic acid itself – require both strands of the nucleic acid. The fact that there exists some ***possible*** uses of a nucleic acid that do not require its complement is not an adequate basis for restriction of claims directed to this subject matter where the claims are not so limited so that the claimed subject matter can only be put to such different, possible uses.

In finding applicants' point that a polynucleotides and its complement are not distinct since the structure of one strand necessarily and predictably imposes a structure upon the other, the Office stated such was not persuasive, since:

> The same argument can be made for a receptor and a ligand, an antibody and an antigen, and an enzyme and substrate, and yet a receptor is usually chemically distinct from a ligand thereto, as is a [sic] antibody an antigen as well as an enzyme and substrate. Therefore, the simple fact that two compounds are capable of forming a complex is not a basis for the conclusion that those two compounds are patentably indistinct.

Id.

While this argument shows the Examiner's thoughtful consideration of the issues, it is overbroad in its conclusion. The structure imposed upon a nucleic acid complement by the structure of the nucleic acid to which it is complementary is far more definite and predictable than the structure imposed upon the receptor-ligand, antibody-antigen, and enzyme-substrate relationships.

Applicants note that MPEP §806 sets out the general principles relating to distinctness or independence may be summarized as follows:

> (A) Where inventions are independent (i.e., no disclosed relation therebetween), restriction to one thereof is ordinarily proper, though a reasonable number of species may be claimed when there is an allowed (novel and unobvious) claim generic thereto.
>
> (B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper.
>
> (C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.

In the present case, there is a disclosed relation between the claimed nucleic acid and its complement – specifically, the complement has a structure that is dependent upon the structure of the claimed nucleic acid. Therefore restriction is not supported by (A).

With respect to reason (B), the claimed invention are both related as disclosed and related as claimed. Complementary nucleic acid is related in sequence, since the structure of one sequence necessarily and predictably imposes a structure upon the other. Similarly, nucleic acid probes must share structural features – e.g., at least 10 nucleotides of a recited sequence or its complement – in order to be useful in detection of the sense or antisense nucleic acid strand. Thus, restriction is not supported by reason (B).

Finally, with respect to (C), the recited nucleic acid and its complement – as well as probes for detection of the nucleic acid and its complement – are related as disclosed but are not distinct as claimed. The subject matter claimed with respect to any one SEQ ID NO all flow from a single discovery – i.e., the discovery of a human VDR isoform having the recited sequence. The recited SEQ ID NO can be used in connection with its complement to provide for expression of the encoded protein. Probes based upon the recited SEQ ID NO or its complement can be used to detect the mRNA product of expression of such isoforms.

In view of the above, applicants request withdrawal of the Restriction Requirement to the extent that examination of nucleic acids and their complements, including probes, are included in the same Group. Specifically, applicant request that the Restriction Requirement be withdrawn and a new Restriction Requirement issued as set out below:

Group I:	Claims 1-4, 9-14, and 20-24, drawn to an isolated polynucleotide comprising exon 1d (SEQ ID NO:1), as well as complements, probes and antisense polynucleotides;
Group II:	Claims 5-14 and 20-24, drawn to an isolated polynucleotide comprising exon 1f (SEQ ID NO:5), as well as complements, probes and antisense polynucleotides;
Group III:	Claims 5-14 and 20-24, drawn to an isolated polynucleotide comprising exon 1e (SEQ ID NO:6), as well as complements, probes and antisense polynucleotides;
Group IV:	Claim 15, drawn to a human protein;
Group V:	Claim 16, drawn to an antibody;
Group VI:	Claim 17, drawn to a transgenic animal;

Since the Restriction between the sequences should not have been made, this Petition has been necessitated by an error of the Office. Accordingly, applicants request that the fee paid for consideration of this Petition be refunded to the Deposit Account.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815 Order No. RICE-014.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: June 4, 2003

By: _____
Carol L. Francis
Registration No. 36,513

BOZICEVIC, FIELD & FRANCIS LLP
200 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

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